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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,965	06/09/2005	Sidney Liang	1626 WO/US	6899

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Mallinckrodt Inc
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St Louis, MO 63134

EXAMINER

DAVIS, BRIAN J

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/537,965

Applicant(s)

LIANG, SIDNEY

Examiner

Brian J. Davis

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17, 19-26 and 29 is/are rejected.
- 7) ☒ Claim(s) 5, 18, 27, 28 and 30-34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/29/05, 12/1/05, 1/13/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: the parentage of the application should appear immediately after the title. MPEP 1893.03(c). Appropriate correction is required.

Information Disclosure Statement

The A2 reference on the 8/29/05 IDS has been lined through as it is drawn to a safety belt - clearly not germane to the instant application. The other lined-through references on that IDS and the 12/1/05 IDS are duplicate entries.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how acetone may be defined as "lower alkanol." While an applicant may be his own lexicographer, applicant may not distort art-recognized terms. *Ex parte Klager*, 132 USPQ 203 (POBA 1959).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 6-13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 2002/0183552 A1, cited by applicant in the IDS. The reference teaches the synthesis of benzhydrylthioacetamide by reacting the corresponding benzhydrylthiocaroxamidine salt with a haloacetamide (chloroacetamide) in a reaction medium comprising water, a water miscible organic solvent (MeOH) and a water soluble basic salt (NaOH), (page 3, Example 1c). Claims 6-11 are included in this rejection as it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33 (CCPA 1937). *In re Russell*, 439 F2d 1228, 169 USPQ 426 (CCPA 1971).

Claims 14-16 and 19-25 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 2002/0183552 A1, cited by applicant in the IDS. The reference teaches the synthesis of benzhydrylthiocarboxamidine bromide by reacting benzhydrol

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and thiourea in the presence of HBr (page 2, Reference Example 1). This reaction is followed by the synthesis of benzhydrylthioacetamide by reacting benzhydrylthiocarboxamidine bromide (formed in the first reaction) with a haloacetamide (chloroacetamide) in a reaction medium comprising water, a water miscible organic solvent (MeOH) and a water soluble basic salt (NaOH), (page 3, Example 1c). The benzhydrylthioacetamide is then oxidized to yield Modafinil (page 3, Reference Example 2). As above, claims 19-24 are included in this rejection as it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality.

Claims 26 and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 2004/075841, cited by applicant in the IDS. The reference teaches the formation of Modafinil form II by reslurrying in dichloroethane (page 10, line 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0183552 A1, cited by applicant in the IDS.

Both applicant's process and the prior art process have been essentially outlined above.

Applicant distinguishes over the cited art in that a potassium salt is explicitly taught. However, one of ordinary skill in the chemical arts at the time of the invention would have considered a potassium salt equivalent to the sodium salt of the prior art – absent unexpected results – given that the two metals are both alkali metals and they (and their salts) would therefore be expected to exhibit similar properties.

Allowable Subject Matter

Claims 5, 18, 27, 28 and 30-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 **BRIAN DAVIS**
PRIMARY EXAMINER

Brian J. Davis
December 9, 2006